III. REMARKS

A. Amendments to the Specification

Paragraph [0123] of the specification was amended to remove the first sentence.

It is respectfully submitted that no new matter was introduced by virtue of this amendment.

B. Status of the claims

Claims 8-11, 13, 14, 16, 20, 22-24, 29, 30, 32-38, and 40-55 are pending, and are encompassed by the elected invention (including the elected species).

C. Specification

In the Office Action the Examiner stated:

> In paragraph 0123, applicant stated that 'The pharmacokinetic information for loratadine is available in the literature.' However, applicant did not provide any source for this information. Applicants are requested to provide on record the source of the information regarding pharmacokinetics of loratadine.

Office Action, page 2.

Paragraph [0123] has been amended without prejudice to remove the sentence referred to by the Examiner. Accordingly, it is respectfully submitted that the Examiner's request is rendered moot by this amendment.

D. Rejection under 35 U.S.C. § 103

Claims 8-11, 13, 14, 16, 20-24, 29, 30, 32-38, and 40-49 were rejected under 35 U.S.C. § 103 (a) over U.S. Patent No. 4,910,205 to Kogan et al. ("the Kogan reference"), purportedly "in view of applicants' admission in paragraph

0123 and U.S. Patent No. 5,968,547 to Reder et al." *Office Action, page 3.* The Examiner stated on page 8 of the Office Action that "[t]he claimed plasma level of loratadine of the prior [art] is are expected to be same as those disclosed by the prior art since the prior art teaches the same daily and hourly delivery rate of loratadine for the same period of time as instantly claimed."

The rejection is respectfully traversed. Applicants respectfully submit that it was shown in the response filed on February 17, 2009, that steady state plasma levels of loratadine calculated from the flux at approximate steady state of the Final Gel of the Kogan reference are different and do not overlap with the plasma level of loratadine at steady state recited in independent claims 8, 20 and 46.

Specifically, it was shown that the steady state loratadine concentration after administration of the Final Gel of the Kogan reference at approximately steady state is 0.48 ng/ml, when calculated using the first formula given in paragraph [0123] of the specification (i.e., the dosing rate is "a product of the steady state concentration of loratadine and a representative clearance rate"), or 0.69 ng/ml, when calculated using the second formula given in paragraph [0123] of the specification (i.e., the dosing rate is equal to "[t]he product of steady state concentration, volume of distribution and elimination rate constant").

Applicants respectfully submit that these calculations clearly show that the claimed steady state plasma level of loratadine (i.e., about 3 ng/ml) is not the same as the calculated steady state loratadine concentrations for the Final Gel of the Kogan reference (i.e., 0.48 ng/ml or 0.69 ng/ml).

In response to the Examiner's statement on page 8 of the Office Action that "it is noticed [that] Kogan teaches mean average release rate from 1.4 $\mu g/cm^2/hr$ to 14 $\mu g/cm^2/hr$ and applicant claim mean average release rate from 1.8 $\mu g/cm^2/hr$ to 9.9 $\mu g/cm^2/hr$," Applicants respectfully note that the flux rates in Table I of the Kogan reference are "at approximate **steady state**," rather than at " 24 hours; ... 48 hours; ... 72

hours; and ... 96 hours" as recited in independent claims 8, 20 and 46. Applicants therefore submit that the Examiner's comparison is inappropriate.

Applicants further submit that there is no indication in the cited references that the release profile of loratadine described in the Kogan reference is unacceptable, or that the specific release profiles recited in the present claims are desirable. Applicants therefore submit that the cited references would not have motivated a person of ordinary skill to arrive at the invention recited in present independent claims 8, 20 and 46.

In response to the Examiner's statement on page 12 of the Office Action that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious," Applicants respectfully submit that "a plasma level of loratadine at steady state of about 3 ng/ml" is not taught or suggested by the cited references. Accordingly, Applicants submit that the combination of the cited references does not teach or suggest each and every element of independent claims 8, 20 and 46.

For the foregoing reasons and the reasons presented in the response filed on February 17, 2009, Applicants respectfully submit that the invention recited in independent claims 8, 20 , 46 and their dependent claims is not rendered obvious by the combination of the cited references.

Withdrawal of the rejection is therefore respectfully requested.

IV. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully invited to contact the undersigned by telephone, if a telephone interview would advance prosecution of the present application.

Respectfully submitted,
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